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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,836	05/16/2001	Han Oh Park	024018/0105	9171
7	590 12/18/2001	•		
Stephen A. Bent			EXAMINER	
FOLEY & LARDNER Washington Harbour			WARE, DEBORAH K	
3000 K Street, N.W., Suite 500 Washington, DC 20007-5109			ART UNIT	PAPER NUMBER
··· uog.o, D	2000. 0103		1651	·
			DATE MAILED: 12/18/2001	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/855,836

Applicant(s)

Park et al

Examiner

Ware

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The MAILING DATE of this communication app ars o	
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET	TO EXPIRE MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION Extensions of time may be available under the provisions of 37 CFR 1.136	(a). In no event, however, may a reply be timely filed
 after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply v be considered timely. 	vithin the statutory minimum of thirty (30) days will
 If NO period for reply is specified above, the maximum statutory period will communication. 	apply and will expire SIX (6) MONTHS from the mailing date of this
 Failure to reply within the set or extended period for reply will, by statute, c Any reply received by the Office later than three months after the mailing of earned patent term adjustment. See 37 CFR 1.704(b). 	ause the application to become ABANDONED (35 U.S.C. § 133). late of this communication, even if timely filed, may reduce any
Status	
1) X Responsive to communication(s) filed on <u>Sep 13, 200</u>	01
2a) ☐ This action is FINAL . 2b) ☒ This action	
3) Since this application is in condition for allowance excectors closed in accordance with the practice under Ex parter.	
Disposition of Claims	internal managing in the counting
	is/are pending in the applica
	is/are withdrawn from considera
5)	is/are allowed.
6) 🛛 Claim(s) <u>1-45</u>	is/are rejected.
7)	is/are objected to.
8) Claims	are subject to restriction and/or election requirem
Application Papers	·
9) The specification is objected to by the Examiner.	•
10) The drawing(s) filed on is/are	
11) The proposed drawing correction filed on	is: a∏ approved b)⊡disapproved.
12) \square The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
13) 🛛 Acknowledgement is made of a claim for foreign priority	y under 35 U.S.C. § 119(a)-(d).
a)⊠ All b) □ Some* c) □None of:	
 Certified copies of the priority documents have be 	en received.
2. Certified copies of the priority documents have be	
3. Copies of the certified copies of the priority document application from the International Bureau (Figure 1997).	PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the ce 14) Acknowledgement is made of a claim for domestic prio	•
Toknowledgement is made of a diam for domestic prior	, 225. 50 5.5.5. 3
Attachment(s)	_
	8) Interview Summary (PTO-413) Paper No(s).
	9) Notice of Informal Patent Application (PTO-152)
17) X Information Disclosure Statement(s) (PTO-1449) Paper No(s)32	0) [_] Other:

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Claims 1-45 are presented for examination on the merits.

- 1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Further, the information disclosure statement filed September 13, 2001, has been received and the reference considered which were submitted therewith as indicated on the enclosed copy of the PTO-1449 Form.
- 2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The two strains may exist in nature since the claims do not describe a biologically pure strain of either of the Lactobacillus or Acetobacter. Therefore, inclusion of this language is suggested to overcome this rejection.

4. Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the



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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism is required and recited in each of the claims, it is essential to the whole invention as recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

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- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
 - (d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CAR § 1.807(b) which states:

- (b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:
- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CAR § 1.809(d) which states:

- (d) For each deposit made pursuant to these regulations, the specification shall contain:
- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.
- 5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 3-45 are rejected under 35 U.S.C. 102(a) as being anticipated by EP 0956867A1, cited on the enclosed PTO-892 Form.

Claims are drawn to Lactobacillus and methods of using the strain in a pharmaceutical for treating a variety of things including diabetes.

EP 0956867A1 teaches Lactobacillus and methods of using the strain in a pharmaceutical for treating a variety of things including diabetes. Diabetes often causes weight gain and obesity. Thus, by using the pharmaceutical to treat diabetes the treatment of other associated symptoms to this disease is inherent to the teachings of the reference.

The claims are identical to the disclosure of the EP reference and are therefore, considered to be anticipated by the teachings therein.

7. Claim 2 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Valla, as cited on the PTO-1449 Form.

Claim is drawn to Acetobacter strain.

Valla teaches Acetobacter strain.

Thus, the claim is identical to the teachings of Valla and is considered to be clearly anticipated by the cited reference.

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All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Deborah K. Ware

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December 12, 2001